Retrospective non-interventional chart review study of the dosing and short-term clinical outcomes of patients with Crohn’s Disease treated with ustekinumab in Finland (FINUSTE2)

First published: 13/08/2019

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS30920

Study ID

43159

DARWIN EU® study

No

Study countries

☐ Finland

Study description

The study is an observational, retrospective, non-interventional patient chart review study, whose population is adult patients with confirmed Crohn’s disease (CD) and who have initiated an intravenous ustekinumab therapy during years 2017 and 2018. The primary objective of the study is to investigate the real-life dosing patterns and the positioning of ustekinumab in the treatment of CD patients in Finland. The secondary objectives are to determine the proportion of patients continuing treatment with ustekinumab at the time of data collection, to evaluate the change in effectiveness from baseline (measured by Harvey-Bradshaw index, endoscopic score SES-CD) at 16 weeks, 1 year, 1.5 years, 2 years, and at the end of study period, and to determine the reasons for ustekinumab treatment discontinuation. This study is an extension amendment of the original FINUSTE study (EUPAS24728). In the amendment, data collection time was extended by one year (until 30.4.2019), and four new study sites were included in the study. Data collection points of 1 year, 1,5 years and 2 years were added as well, along with some minor changes. Although FINUSTE2 is not an independent study, it is registered as a separate study for clarity and transparency.

Study status

Finalised

Research institutions and networks

Institutions

Helsinki University Hospital (HYKS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

A list of participating centres is provided in a separate document in section 19. Please see the attachment

Contact details

Study institution contact

Erkki Soini erkki.soini@esior.fi

Study contact

erkki.soini@esior.fi

Primary lead investigator

Taina Sipponen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/03/2019

Study start date

Actual: 02/05/2019

Data analysis start date
Planned: 26/08/2019

Actual: 12/08/2019

Date of final study report
Planned: 30/09/2020

Actual: 05/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen-Cilag AB

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

EUPAS24728 (FINUSTE)

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of the study is to investigate the real-life dosing patterns and the positioning of ustekinumab in the treatment of CD patients in Finland

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, non-interventional, retrospective patient chart review study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

USTEKINUMAB

Medical condition to be studied

Crohn's disease

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

150

Study design details

Outcomes

The primary outcome of the study is the ustekinumab treatment and dose adjustments (mean and median ustekinumab dose and dosing interval), Secondary outcomes include disease activity measured by Harvey-Bradshaw index, and disease activity, measured by SES-CD. Both are measured at 0 and 16 weeks, 1 year, 1.5 years, 2 years, and at the end of study period.

Data analysis plan

To present the observed variables, frequencies and statistical testing for each sensible comparison. To perform statistical tests on univariate comparisons, the $\chi 2$ test (for categorical data) and parametric tests, such as the analysis of variance (ANOVA, for continuous data) are considered if the sample size is sufficient. E.g. with less than 30 observations in a group with continuous variable being compared, non-parametric tests are considered. Where feasible, point estimates with interval estimates (confidence intervals or standard errors) are presented. P-value lower than 0.050 is considered statistically significant.

Documents

Study, other information

190812_research_centres.pdf(48.78 KB)

Study publications

Sipponen T, af Björkesten C-G, Hallinen T et al. A nationwide real-world study ...

af Björkesten C-G, Ilus T, Hallinen T et al. Objectively assessed disease activ...

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Routine secondary care electronic patient registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No